

IN THE CLAIMS

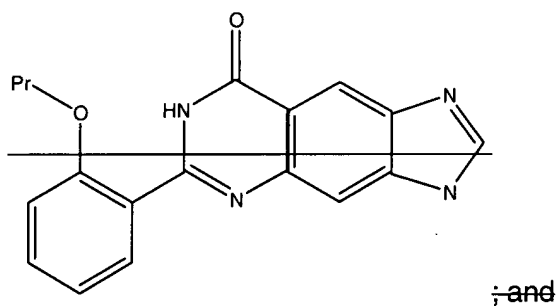
1. (Canceled) A method of treating pulmonary hypertension in a patient which comprises treating the patient with an effective amount of a PDE5 inhibitor selected from the group consisting of:

a) ~~sildenafil~~

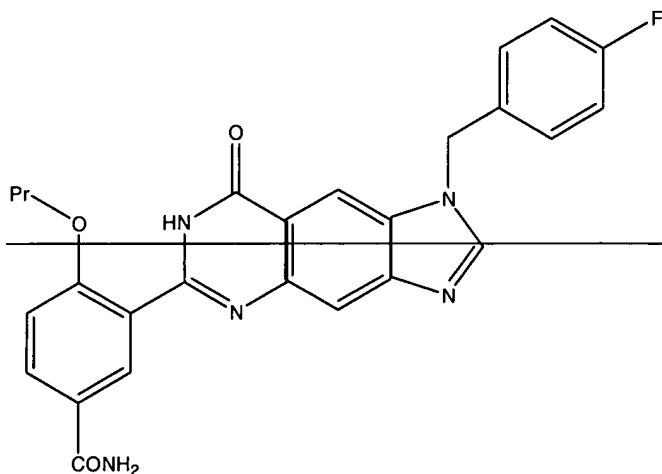
b) ~~(6R, 12aR) 2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2'1':6,1]pyrido[3,4-b]indole-1,4-dione;~~

e) ~~2-[2-ethoxy-5-(4-ethyl-piperazin-1-yl-1-sulphonyl)-phenyl]-5-methyl-7-propyl-3H-imidazo[5,1-f][1,2,4]triazin-4-one;~~

~~_____d)~~



~~_____e)~~



~~_____ or a pharmaceutically acceptable salt, solvate or polymorph; or a pharmaceutical composition thereof.~~

2. - 6. (Cancelled)

7. (Cancelled) A method according to claim 1 wherein the PDE5 inhibitor is administered orally.

8. (Currently Amended) A method according to claim 4 21 wherein the salt is PDE5 inhibitor is sildenafil citrate.

9. (Currently Amended) A method according to claim 4 21 wherein sildenafil the PDE5 inhibitor is inhaled.

10. (Currently Amended) A method according to claim 4 21 wherein the salt PDE5 inhibitor is sildenafil mesylate.

11. - 20. (Cancelled)

21. (Previously Presented) A method of treating pulmonary hypertension in a patient consisting of treating the patient with an effective amount of sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof.

22. (Previously Presented) The method of claim 21, wherein the treatment is oral administration.

23. (Previously Presented) The method of claim 22, wherein the effective amount is less than 50 mg per day.

24. (Previously Presented) The method of claim 22, wherein the effective amount is less than 20 mg per day.

25. (Previously Presented) The method of claim 22, wherein the effective amount is less than 10 mg per day.

26. (Previously Presented) The method of claim 22, wherein the effective amount is from 1-10 mg per day.
27. (Previously Presented) The method of claim 21, wherein the patient is an adult.
28. (Previously Presented) The method of claim 22, wherein the patient is an adult.
29. (Previously Presented) The method of claim 23, wherein the patient is an adult.
30. (Previously Presented) The method of claim 24, wherein the patient is an adult.
31. (Previously Presented) The method of claim 25, wherein the patient is an adult.
32. (Previously Presented) The method of claim 26, wherein the patient is an adult.
33. (Previously Presented) The method of claim 21, wherein the treatment is parenteral administration.
34. (Previously Presented) The method of claim 21, wherein the treatment is intravenous administration.
35. (Previously Presented) The method of claim 34, wherein the effective amount is less than 50 mg per day.
36. (Previously Presented) The method of claim 34, wherein the effective amount is less than 20 mg per day.

37. (Previously Presented) The method of claim 34, wherein the effective amount is less than 10 mg per day.

38. (Previously Presented) The method of claim 34, wherein the effective amount is from 1-10 mg per day.

39. (Previously Presented) The method of claim 34, wherein the patient is an adult.

40. (Previously Presented) The method of claim 35, wherein the patient is an adult.

41. (Previously Presented) The method of claim 36, wherein the patient is an adult.

42. (Previously Presented) The method of claim 37, wherein the patient is an adult.

43. (Previously Presented) The method of claim 38, wherein the patient is an adult.

44. (Previously Presented) A method of treating pulmonary hypertension in a patient comprising treating the patient with an effective amount of sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof, and wherein the treatment is carried out without administration of prostacyclins, oxygen, calcium channel blockers, endothelin antagonists, iloprost, adenosine and/or nitric oxide.

45. (Previously Presented) The method of claim 44, wherein the treatment is oral administration.

46. (Previously Presented) The method of claim 45, wherein the patient is an adult.

47. (Previously Presented) The method of claim 46, wherein the effective amount is less than 50 mg per day.

48. (Previously Presented) The method of claim 46, wherein the effective amount is less than 20 mg per day.

49. (Previously Presented) The method of claim 46, wherein the effective amount is less than 10 mg per day.

50. (Previously Presented) The method of claim 46, wherein the effective amount is from 1-10 mg per day.

51. (Previously Presented) The method of claim 44, wherein the treatment is parenteral administration.

52. (Previously Presented) The method of claim 44, wherein the treatment is intravenous administration.

53. (Previously Presented) The method of claim 52, wherein the patient is an adult.

54. (Previously Presented) The method of claim 53, wherein the effective amount is less than 50 mg per day.

55. (Previously Presented) The method of claim 53, wherein the effective amount is less than 20 mg per day.

56. (Previously Presented) The method of claim 53, wherein the effective amount is less than 10 mg per day.

57. (Previously Presented) The method of claim 53, wherein the effective amount is from 1-10 mg per day.

58. (Previously Presented) The method of claim 44, wherein the patient is a child suffering from pulmonary hypertension post operatively or due to respiratory distress syndrome or neonatal hypoxia.

59. (Previously Presented) The method of claim 58, wherein the effective amount is less than 50 mg per day.

60. (Previously Presented) The method of claim 58, wherein the effective amount is less than 20 mg per day.

61. (Previously Presented) The method of claim 58, wherein the effective amount is less than 10 mg per day.

62. (Previously Presented) The method of claim 58, wherein the effective amount is from 1-10 mg per day.

63. (Previously Presented) A method of treating pulmonary hypertension in a patient comprising treating the patient with an effective amount of orally-administered sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof, to selectively reduce pulmonary vascular resistance to a greater extent than systemic vascular resistance in the patient.

64. (Previously Presented) The method of claim 63, wherein the patient is an adult.

65. (Previously Presented) The method of claim 64, wherein the adult suffers from primary pulmonary hypertension.

66. (Previously Presented) The method of claim 65, wherein the effective amount is less than 50 mg per day.

67. (Previously Presented) The method of claim 65, wherein the effective amount is less than 20 mg per day.

68. (Previously Presented) The method of claim 65, wherein the effective amount is less than 10 mg per day.

69. (Previously Presented) The method of claim 65, wherein the effective amount is from 1-10 mg per day.

70. (Previously Presented) The method of claim 64, wherein the adult suffers from secondary pulmonary hypertension.

71. (Previously Presented) The method of claim 70, wherein the effective amount is less than 50 mg per day.

72. (Previously Presented) The method of claim 70, wherein the effective amount is less than 20 mg per day.

73. (Previously Presented) The method of claim 70, wherein the effective amount is less than 10 mg per day.

74. (Previously Presented) The method of claim 70, wherein the effective amount is from 1-10 mg per day.

75. (Previously Presented) A method of treating pulmonary hypertension in a child afflicted with pulmonary hypertension post operatively, due to respiratory distress syndrome, or due to neonatal hypoxia, which comprises treating the child with an effective amount of sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof.

76. (Previously Presented) The method of claim 75, wherein the treatment is intravenous administration.

77. (Previously Presented) The method of claim 75, wherein the treatment is carried out without administration of prostacyclins, oxygen, calcium channel blockers, endothelin antagonists, iloprost, adenosine and/or nitric oxide.

78. (Previously Presented) A method of treating pulmonary hypertension due to congenital heart disease in a patient, which comprises treating the patient with an effective amount of sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof.

79. (Previously Presented) The method of claim 78, wherein the patient is an adult.

80. (Previously Presented) The method of claim 79, wherein the effective amount is less than 50 mg per day.

81. (Previously Presented) The method of claim 79, wherein the effective amount is less than 20 mg per day.

82. (Previously Presented) The method of claim 79, wherein the effective amount is less than 10 mg per day.

83. (Previously Presented) The method of claim 79, wherein the effective amount is from 1-10 mg per day.

84. (Previously Presented) The method of claim 78, wherein the patient is a child.

85. (Previously Presented) The method of claim 84, wherein the effective amount is less than 50 mg per day.

86. (Previously Presented) The method of claim 84, wherein the effective amount is less than 20 mg per day.

87. (Previously Presented) The method of claim 84, wherein the effective amount is less than 10 mg per day.

88. (Previously Presented) The method of claim 84, wherein the effective amount is from 1-10 mg per day.

89. (Previously Presented) A method of treating pulmonary hypertension due to chronic hypoxic lung disorder in a patient, which comprises treating the patient with an effective amount of sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof.

90. (Previously Presented) The method of claim 89, wherein the effective amount is less than 50 mg per day.

91. (Previously Presented) The method of claim 89, wherein the effective amount is less than 20 mg per day.

92. (Previously Presented) The method of claim 89, wherein the effective amount is less than 10 mg per day.

93. (Previously Presented) The method of claim 89, wherein the effective amount is from 1-10 mg per day.

94. (Previously Presented) A method of treating pulmonary hypertension due to chronic obstructive pulmonary disease in a patient, which comprises treating the patient with an effective amount of sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof.

95. (Previously Presented) The method of claim 94, wherein the effective amount is less than 50 mg per day.

96. (Previously Presented) The method of claim 94, wherein the effective amount is less than 20 mg per day.

97. (Previously Presented) The method of claim 94, wherein the effective amount is less than 10 mg per day.

98. (Previously Presented) The method of claim 94, wherein the effective amount is from 1-10 mg per day.

99. (Previously Presented) A method of treating pulmonary hypertension in a patient comprising treating the patient with an effective amount of sildenafil or a pharmaceutically acceptable salt of sildenafil, or a pharmaceutical composition thereof, and wherein the treatment is carried out without administration of nitric oxide.

100. (Previously Presented) The method of claim 99, wherein the patient is an adult.

101. (Previously Presented) The method of claim 100, wherein the effective amount is less than 50 mg per day.

102. (Previously Presented) The method of claim 100, wherein the effective amount is less than 20 mg per day.

103. (Previously Presented) The method of claim 100, wherein the effective amount is less than 10 mg per day.

104. (Previously Presented) The method of claim 100, wherein the effective amount is from 1-10 mg per day.

105. (Previously Presented) The method of claim 100, wherein the patient is a child.

106. (Previously Presented) The method of claim 105, wherein the child is suffering from pulmonary hypertension due to congenital heart disease, post operative pulmonary hypertension, or due to respiratory distress syndrome or neonatal hypoxia.

107. (Previously Presented) The method of claim 106, wherein the effective amount is less than 50 mg per day.

108. (Previously Presented) The method of claim 106, wherein the effective amount is less than 20 mg per day.

109. (Previously Presented) The method of claim 106, wherein the effective amount is less than 10 mg per day.

110. (Previously Presented) The method of claim 106, wherein the effective amount is from 1-10 mg per day.

111. (Previously Presented) The method of claim 21, wherein the patient suffers from primary pulmonary hypertension.

112. (Previously Presented) The method of claim 21, wherein the patient suffers from secondary pulmonary hypertension.

AMENDMENT

Applicants respectfully request entry of the amendments hereinabove, reconsideration of the Office Action mailed on March 31, 2004 and allowance of the application.

Applicants were contacted on or about October 25, 2004 by Examiner Dwayne C. Jones regarding the status of the instant application. Applicants herewith include a PETITION FOR REVIVAL (Form PTO/SB/64), the Petition Fee, the instant amendment and the required statement.

Applicants herewith submit a Supplemental Disclosure Statement with some new references and some references that were previously submitted but not checked off by the Examiner.

As a preliminary manner, Applicant(s) request that the Examiner carefully consider the entire text of each reference. It is requested that the references listed on the form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing on this application (M.P.E.P. 1302.12).

Applicants also direct the Examiner's attention to John J. Lepore et al., Circulation, Supplement 1, Vol. 100, No. 18 no. 1247, Nov. 2, 1999 "Sildenafil is a Pulmonary Vasodilator Which Augments and Prolongs Vasodilation by Inhaled Nitric Oxide in Patients with Pulmonary Hypertension" and Andrew M. Atz, et al., Anesthesiology, v.91, no. 1, July 1999, "Sildenafil Ameliorates Effects of Inhaled Nitric Oxide Withdrawal".

Applicants also urge the Examiner to carefully consider all the other references listed in the Information Disclosure Statements of record and those submitted herewith.